Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2019/032 Issued: 03 October 2019 at 11:00

Breathing circuit swivel elbow – recall due to risk of cracks forming before or during use

Summary

Manufactured by Intersurgical, used in devices made by other companies: cracks in swivel elbow connectors may lead to prescribed ventilation not being delivered.

Action

- Note that the swivel elbow is a component used in a number of breathing circuits, distributed by several companies.
- Immediately quarantine all affected lot numbers listed in Field Safety Notice 1 (FSN1) from Intersurgical and FSN2 from Breas Medical and do not use.
- Contact the manufacturer of the identified devices using the response form on the appropriate FSN to arrange collection or confirm destruction of all affected devices.
- If you do not have affected devices left in stock, confirm this with the corresponding manufacturer using the response form on their FSN
- Report suspected or actual adverse events involving these devices through your local incident reporting system and/or your national incident reporting authority as appropriate: England, Scotland, Northern Ireland, Wales. You should also report directly to manufacturers if your local or national systems do not.

Action by
All healthcare professionals who are responsible for or who use these devices.

Deadlines for actions
Actions underway: 10 October 2019
Actions complete: 31 October 2019

Medical Device Safety Officers (in England): ask the manufacturer to add you to their distribution list for field safety notices (FSNs). This is to help with reconciliation.

Remember: if your organisation receives an FSN from a manufacturer, always act on it. **Do not wait** for a communication from MHRA.

Department of Health
An Roinn Sláinte
Männystrie O Poustie
www.health-ni.gov.uk

NHS National Services Scotland

Llywodraeth Cymru Welsh Government

Manufacturer contacts

Intersurgical
Tel: 01481 747702
Email: SJF@Intersurgical.co.uk

Device details

This device is used as a component in a number of different breathing circuits, made by multiple manufacturers.
Ensure that all circuits are inspected carefully for affected components.

Distribution

If you are responsible for cascading these alerts in your organisation, these are our suggested distribution lists.

Trusts (NHS boards in Scotland)

CAS and NICAS liaison officers for onward distribution to all relevant staff including:

- A&E consultants
- A&E departments
- A&E directors
- A&E nurses
- Adult intensive care units
- Ambulance services directors
- Ambulance staff
- Anaesthesia, directors of
- Anaesthetic medical staff
- Anaesthetic nursing staff
- Anaesthetists
- Anti-coagulation clinics
- Cardiothoracic departments
- Cardiothoracic surgeons
- Cardiothoracic surgery directors
- Chief pharmacists
- Chiropodists
- Clinical governance leads
- Clinical perfusionists
- Community defibrillation officers
- Community hospitals
- Coronary care departments
- Coronary care nurses
- Day surgery units
- EBME departments
- ENT departments
- ENT medical staff
- ENT services, directors of
- Equipment stores
- Equipment libraries and stores
- Gastroenterology departments
- Gastroenterology, directors of
- Gastro-intestinal surgeons

- General surgeons
- General surgery
- General surgical units, directors of
- Intensive care medical staff/paediatrics
- Intensive care nursing staff (adult)
- Intensive care nursing staff (paediatric)
- Intensive care units
- Intensive care, directors of
- Maxillofacial departments
- Medical directors
- Medical libraries
- Medical physics departments
- Microbiologists
- Neonatal nurse specialists
- Neonatology departments
- Neonatology directors
- Obstetricians
- Obstetrics and gynaecology departments
- Obstetrics and gynaecology directors
- Obstetrics departments
- Obstetrics nurses
- Operating department practitioners
- Oral surgeons
- Orthopaedic surgeons
- Paediatric intensive care units
- Paediatric medicine, directors of
- Paediatric nurse specialists
- Paediatric oncologists
- Paediatric surgeons
- Paediatric surgery, directors of
- Palliative care teams
- Paramedics
- Patient transport managers
- Purchasing managers
- Special care baby units
- Supplies managers
- Theatre managers
- Theatre nurses
- Theatres
- Urological surgeons
- Urological surgery, directors of
- Urology departments

Independent distribution

Establishments registered with the Care Quality Commission (CQC) (England only)

- Adult placement
- Hospices
- Hospitals in the independent sector
- Independent treatment centres
- Nursing agencies
- Private medical practitioners

Please note: CQC and OFSTED do not distribute these alerts. Independent healthcare providers and social care providers can sign up to receive MDAs directly from the Central Alerting System (CAS) by sending an email to: safetyalerts@mhra.gov.uk and requesting this facility.

Enquiries

England

Send enquiries about this notice to MHRA, quoting reference number **MDA/2019/032** or 2019/007/019/291/001.

Technical aspects

Ben Satchell or Emma Rooke, MHRA

Tel: 020 3080 6000

Email: DSS-TM@mhra.gov.uk

Clinical aspects

Devices Clinical Team, MHRA

Tel: 020 3080 7274

Email: dct@mhra.gov.uk

To report an adverse incident involving a medical device in England use the Yellow Card reporting page

Northern Ireland

Northern Ireland Adverse Incident Centre (NIAIC), CMO Group, Department of Health (Northern Ireland)

Tel: 028 9052 3868

Email: niaic@health-ni.gov.uk

To report an adverse incident involving a medical device in Northern Ireland use the forms on the website.

Alerts in Northern Ireland are distributed via the NICAS system.

Scotland

Incident Reporting and Investigation Centre (IRIC), Health Facilities Scotland, NHS National Services Scotland

Tel: 0131 275 7575

Email: nss.iric@nhs.net

To report an adverse incident involving a medical device in Scotland, email IRIC to request a webform account.

For more information, or if you can't access the webform, visit the website: how to report an adverse incident

Wales

Population Healthcare Division, Welsh Government

Tel: 03000 255278 / 03000 255510

Email: haz-aic@gov.wales

To report an adverse incident involving a medical device in Wales, use the Yellow Card reporting page and follow specific advice for reporting in Wales in MDA/2004/054 (Wales).